

plasco, inc.

4080 MORRISON DRIVE • GURNEE, ILLINOIS 60031 • 708-662-4400

MAR 20 1996

510(k) SUMMARY

1. Submitted By:

K953414

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2. Date Prepared: 3/19/96

3. Name of Device:

Proprietary Name: CPR MICROMASK™ with Oxygen Inlet
Classification Name: Valve, Non-Rebreathing
Common/Usual Name: Exhaled-air Pulmonary Resuscitator with Filter

4. Equivalent device:

Laerdal Medical Pocket Mask, Cat. No. 83-00-03 (K861401)

5. Device description:

The configuration of this pocket-sized device is a cushioned face mask used to enclose the patients nose and mouth. A one-way valve allows the rescuer to provide exhaled air to the patient. The oxygen port will allow oxygen enhancement of the rescuer's exhaled air. Expired air and/or fluids from the patient is vented away from the rescuer due to the one-way valve and an alternate venting route.

The device comes in one size and is designed for adults but can be used on infants. By rotating the mask 180 degrees and placing the nose portion just below the infants lower lip, the wider portion of the cushion rests on the forehead. The repositioning of the mask and the soft material of the mask cushion allows for a complete seal of the mask cushion to an infants facial contours.

The device is non-sterile. It normally will be packaged in a polybag which may be placed in a zippered nylon pouch.

This device is not intended for use by persons not trained in basic life saving skills or those with only a basic bystander course.

6. Device use:

A device used for mouth-to-mask treatment of respiratory failure.

7. The CPR MICROMASK with Oxygen Inlet performs the same function and is technologically equivalent to the Laerdal Medical Pocket Mask, Cat. No. 83-00-03.

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510(k) SUMMARY - Page 2

8. Performance Testing:
The CPR MICROMASK with Oxygen Inlet was found equivalent to the Laerdal Medical Pocket Mask for the following:

FLOW RESISTANCE
FACE MASK TRANSPARENCY
FACE SEALING
EFFECT OF VOMITUS AND BARRIER EFFECTIVENESS
DEAD SPACE
EFFECTS OF TEMPERATURE
POSSIBILITY OF MISASSEMBLY
HUMAN FACTORS DESIGN AND INSTRUCTIONS
SUPPLEMENTAL OXYGEN

9. The major patient/rescuer contact components complies with the Tripartite Biocompatibility Guidance for Medical Devices.